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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/822,849	03/29/2001	Gordon G. Wong	GIN-6403	8494

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EXAMINER
EINSMANN, JULIET CAROLINE

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 10/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 07-01)

Office Action Summary	Application No.	Applicant(s)	
	09/822,849	WONG ET AL.	
	Examiner	Art Unit	
	Juliet C Einsmann	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 August 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *7-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of group 1, claims 1-6 with respect to SEQ ID NO: 1, in Paper No. 8 is acknowledged. Applicant's comments regarding rejoinder are noted, and applicant is reminded that in order for rejoinder to occur the method claims must be commensurate in scope with the allowed product and must be pending in the application.

2. It is noted that the claims contain non-elected subject matter. Cancellation of such subject matter will be required prior to allowance of any claims.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-6 are indefinite over the recitation of the phrase "a complement of said sequence" because it is not clear what is meant by the use of the word "a" in this phrase. Clarification would be provided by amending the word "a" to state "the."

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 3-6 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one

skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to an isolated nucleic acid which comprises SEQ ID NO: 1 or comprises a nucleotide sequence which hybridizes to SEQ ID NO: 1, as well as constructs comprising these sequences. Instant SEQ ID NO: 1 is an EST encoding a portion of a secreted protein, but does not appear to be a full length open reading frame. Indeed, the instant specification teaches that the instant ESTs have utility to isolate the full length ORF or genomic DNA of which they are a portion (p. 33). Thus, these claims encompass full length open reading frames and genomic DNA. Furthermore, claims 3, 4, 5, and 6 also encompass allelic variants of SEQ ID NO: 1 as well as related polynucleotides from humans and other species which may or may not encode polypeptides that have similar function to the polynucleotide which SEQ ID NO: 1 encodes a portion of. The specification does not describe a particular function for SEQ ID NO: 1. This large genus of polynucleotides encompassed by the instant claims is represented in the specification by one member, SEQ ID NO: 1. Thus, applicant has express possession of only one species in a genus which comprises many, many different possibilities.

It is noted that in Fiers v. Sugano (25 USPQ2d, 1601), the Fed. Cir. concluded that

> "...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

In the instant application, only the nucleic acid sequence of the disclosed SEQ ID NO: 1 is described. Also, in Vas-Cath Inc. v. Mahurkar (19 USPQ2d 1111, CAFC 1991), it was concluded that:

> "...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed."

In the application at the time of filing, there is no record or description which would demonstrate conception of any polynucleotides modified by addition, insertion, deletion, substitution or inversion with regard to the disclosed SEQ ID No: 1 but possessing one or more nucleotide differences. There is no description of the polynucleotides themselves, nor their function or biological significance.

Claim Rejections - 35 USC § 101

7. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claims 1-6 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial, and credible asserted utility or a well established utility.

The pending claims have been reviewed in light of the the Utility Examination Guidelines and Guidelines for Examination of Patent Applications under 35 U.S.C. 112, first paragraph, "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1092-1111, Friday, January 5, 2001.

The examiner is using the following definitions in evaluating the claims for utility.

"Specific" - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention.

"Substantial" - A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

"Credible" - Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record that is probative of the applicant's assertions. That is, the assertion is an inherently unbelievable undertaking or involves implausible scientific principles.

"Well-established" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art.

The claimed subject matter is not supported by a specific, substantial, and credible utility because the disclosed uses are generally applicable to broad classes of this subject matter. In addition, further characterization of the claimed subject matter would be required to identify or reasonably confirm a "real world" use. The examiner does not find an adequate nexus between the evidence of record and the asserted properties of the claimed subject matter.

The claims are drawn to an isolated nucleic acid which comprises SEQ ID NO: 1 or comprises a nucleotide sequence which hybridizes to SEQ ID NO: 1, as well as constructs comprising these sequences. The specification teaches that SEQ ID NO: 1 was isolated from human adult spleen tissue (Table 2, p. 17 and Table 3, p. 22). Beyond that, the specification provides no further information about SEQ ID NO: 1 in particular. The specification is generally describes 592 different nucleic acid sequences all together.

The specification asserts a wide variety of general utilities for the claimed invention. The specification teaches that "the primary use of the polynucleotides of the invention which are sESTs is as probes for the identification and isolation of full-length cDNAs and genomic DNA molecules which correspond (p. 33)." Further, the specification teaches that the claimed nucleic acid can be useful in research to express recombinant proteins for analysis (p. 33), as a tissue marker, or as a molecular weight marker (p. 33). Furthermore, the specification asserts that each of the disclosed nucleic acids or polypeptides that they encode can be used as a nutritional source or a food supplement (p. 34). However, none of these utilities are specific to the instant polynucleotide or encoded polypeptide because each of them applies to the broad class of nucleic acids or encoded polypeptides. That is, any nucleic acid or encoded polypeptide could be used for these purposes.

The specification further suggests a list of possible biological functions and utilities for the instant polynucleotide and/or encoded polypeptide. For example, the specification teaches that the polynucleotide may encode a cytokine (p. 35), a polypeptide with immune stimulating or immune suppressing activity (p. 36), a polypeptide useful in the regulation of hematopoiesis (p. 41), a polypeptide with tissue growth activity (p. 42), a polypeptide with activin/inhibin activity (p. 44), a polypeptide with chemotactic/chemokinetic activity (p. 45), or a polypeptide with hemostatic or thrombolytic activity (p. 46). The specification teaches that the polynucleotide of the instant invention may be useful in cancer diagnosis and/or therapy (p. 47), or as an anti-inflammatory (p. 46). The possible uses and biological functions cited here are only a few in the extensive list provided by applicant on pages 33-48 of the specification. However, none of these is a substantial or credible utility for the instantly claimed SEQ ID NO: 1 because the specification has provided no reason to believe that instant SEQ ID NO: 1 has or encodes a polypeptide with any of these activities, and the specification provides no guidance or suggestion as to which one or ones of the many suggested utilities are relevant to SEQ ID NO: 1 or the encoded polypeptide. The specification merely suggests that the disclosed polynucleotide and polypeptide "may" have these activities. Further experimentation would be required in order to reasonably confirm any of these utilities as being associated with instant SEQ ID NO: 1 or the polypeptide encoded by instant SEQ ID NO: 1. Thus, these possible utilities are not substantial with regard to the claimed invention.

Finally, the prior art does not provide a well established utility that is specific, substantial, and credible with respect to instant SEQ ID NO: 1. While SEQ ID NO: 1 has a high level of homology to a known full length coding sequence and also to other known EST

molecules (see prior art rejections herein), the prior art does not provide a well known utility for instant SEQ ID NO: 1 that is specific, substantial, and credible.

Applicant should explicitly identify a specific, substantial, and credible utility for the claimed invention and establish a probative relation between any evidence of record and the originally disclosed properties of the claimed invention.

Claims 1-9 and 22-26 also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantial, specific, and credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

The previous utility rejection discusses in depth the scope of the instant claims and the asserted utilities for the instantly claimed polynucleotides. For each of the reasons provided in the utility rejection, the disclosure is insufficient to teach one of skill in the art how to use the invention. A review of *In re Wands,* 8 USPQ2d 1400 (CAFC 1988) clearly points out the factors to be considered in determining whether a disclosure would require undue experimentation and include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and, (8) the breadth of the claims. All of these factors are considerations when determining the whether undue experimentation would be required to use the claimed invention. As is evidence in the discussions *supra,* each of these factors has been carefully considered in the instant grounds of rejection, and it is maintained that undue

experimentation would be required by the skilled artisan to use the instant invention, because the specification fails to provide a specific, credible, and substantial utility for the claimed invention.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims rejected under 35 U.S.C. 102(b) as being anticipated by Jacobs et al. (WO/9845435).

Jacobs et al. teach an isolated polynucleotide comprising a nucleotide sequence which hybridizes to instant SEQ ID NO: 1. The sequence disclosed by Jacobs et al. as SEQ ID NO: 692 shares 99.6% local similarity with instant SEQ ID NO: 1. Specifically, nucleotides 2-254 of the sequence taught by Jacobs et al. are identical to nucleotides 127-254 of instant SEQ ID NO: 1, except for a single mismatch at position 248 of instant SEQ ID NO: 1. This sequence would hybridize to instant SEQ ID NO: 1, even under very high stringency conditions. Jacobs et al. further teach constructs in which their SEQ ID NO: 692 is operably linked to at least one expression control sequence, vectors comprising the sequence, and host cells transformed with such vectors (p. 59, line 28-p. 60, line 3). Thus, the teachings of Jacobs et al. anticipate the rejected claims.

8. Claim 3 is rejected under 35 U.S.C. 102(b) as being anticipated by GenBank Record Accession Y10351, GI: 3021391 (2 April 1998).

The GenBank record provides an isolated polynucleotide comprising a nucleotide sequence which hybridizes to instant SEQ ID NO: 1. The GenBank sequence comprises a sequence 99.3% identity to the full length of SEQ ID NO: 1. Specifically, nucleotides 590-2389 of the sequence taught in the GenBank record are identical to nucleotides 1-1800 of instant SEQ ID NO: 1 except for eight mismatches over the 1800 nucleotide stretch. This sequence would hybridize to instant SEQ ID NO: 1, even under very high stringency conditions.

Conclusion

9. No claims are allowed. Isolated polynucleotides comprising or consisting of instant SEQ ID NO: 1 are free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C. Einsmann whose telephone number is (703) 306-5824. The examiner can normally be reached on Monday through Friday, from 9:00 AM until 4:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Juliet C. Einsmann
Examiner
Art Unit 1634

October 18, 2002

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600